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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,682	10/16/2001	Barney Scott Graham	VBLT:003US/SLH	6636

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,682	GRAHAM ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on January 31, 2005 wherein claims 1-9, 11 and 13-20 have been amended. Claims 10, 12, and 21-50 are cancelled previously.

Currently, claims 1-9, 11 and 13-20 are pending in this application and under examination on the merits.

Applicant's amendment filed January 31, 2005 with respect to the rejection of Claim 1 made under 35 U.S.C. 112 second paragraph for the insufficient antecedent basis for "said subject", of record stated in the Office Action dated August 26, 2004 has been fully considered and found persuasive to remove the rejection since the term "subject" has been removed from the claims. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-6 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for inhibiting infection of a cell in a patient or a patient having an existing viral infection disclosed in the specification employing the particular HMG-CoA reductase inhibitors herein, does not

reasonably provide enablement for inhibiting infection of a cell in a patient who does not have an existing viral infection, for same reasons of record stated in the Office Action dated August 26, 2004, and reiterated in full below.

These claims would be reasonably interpreted as drawn to the method of **preventing** a viral infection in a patient since the patient herein does not have an existing viral infection". Moreover, the limitation " said subject does not have an existing viral infection" in claim 2 is deemed to contradict the subject having a virus in claim 1. Further, if the subject does not have an existing viral infection, the claimed method of inhibiting infection loses its utility or therapeutic purpose, since there is no need to inhibit any viral infection in a subject that does not have an existing viral infection at all.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to the method of inhibiting infection of a cell in a patient who dose not have an existing viral infection or the method of preventing a viral infection in a patient.

The state of the prior art: The skilled artisan would view that the treatment to prevent a viral infection in a patient totally, absolutely, or permanently, is highly unlikely, not even occurring at the first time; or the skilled artisan would view that inhibiting infection of a cell in a patient who dose not have an existing viral infection totally, absolutely, or permanently, is highly unlikely.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that the treatment to prevent a viral infection in a patient totally, absolutely, or permanently, is highly unpredictable, not even occurring at the first time; or the skilled artisan would view that inhibiting infection of a cell in a patient who dose not have an existing viral infection totally, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to prevent a viral infection in a patient totally, absolutely, or permanently, not even occurring at the first time; or showing how inhibit infection of a cell in a patient who dose not have an existing viral infection totally, absolutely, or permanently. Lack of a working example, however, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent

protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test any HMG-CoA reductase inhibitor compounds encompassed in the instant claims to be administered to a patient to prevent a viral infection in a patient totally, absolutely, or permanently, not even occurring at the first time or to inhibit infection of a cell in a patient who dose not have an existing viral infection totally, absolutely, or permanently, with no assurance of success.

Response to Argument

Applicant's arguments filed January 31, 2005 with respect to this rejection of record have been fully considered but are not deemed persuasive as to the scope of enablement of the claimed invention as further discussed below.

First, it is noted that Applicant admits that "[i]f a person is not yet infected with a virus, and is provided with a drug, and then is exposed to a virus, the drug can prevent infection of cells in the individual" (emphasis added, see Applicant's remarks, page 5, 3rd para.).

Applicant also asserts that:

"an existing infection is generally an active infection, with viruses in cells and replicating, whereas a single or a few particles that have yet to infect a cell in a patient are not generally considered an active infection. That is what is meant by the term "not

yet infected." Thus, there is no contradiction with claim 1" (see Applicant's remarks, page 5, 3rd para.).

Nevertheless, Applicant's assertion is not found convincing since claim 2 clearly recites "wherein said patient herein does not have an existing viral infection" (emphasis added). Thus, this limitation in claim 2 is deemed to contradict the patient having a virus in claim 1.

Therefore, as the examiner points out in the previous Office Action, "[t]hese claims would be reasonably interpreted as drawn to the method of **preventing** a viral infection in a patient since the patient herein does not have an existing viral infection".

Applicant further argues that "[a] drug can indeed prevent infection of an uninfected individual by stopping initial infection of cells. Moreover, the claim says nothing about totally, absolutely, or permanently" preventing infection. Applicant's argument is not found persuasive. Given the broadest reasonable interpretation during patent examination, preventing a viral prevention would be reasonably interpreted as total, absolute, or permanent prevention of a virus from a patient or a human patient.

It is the examiner's position that the skilled artisan would view that preventing infection of a cell in a patient who dose not have an existing viral infection totally, absolutely, or permanently is highly unpredictable. The Merck Manual of Diagnosis and Therapy (17th ED) teaches that:

"Several hundred different viruses infect humans. Because many have been only recently recognized, their clinical effects are not fully understood. Many viruses infect host without producing symptoms."; "Only a few of viral disease can be diagnosed

clinically or epidemiologically" (see page 1276); "Vaccination provides no protection when a major antigenic mutation occurs unless the vaccine incorporates the new strain." (emphases added, see page 1288, the left column).

Thus, the teachings of the Merck Manual clearly supports the examiner's position that preventing any infections of a cell in a patient who dose not have an existing viral infection by administering an inhibitor of HMG-CoA reductase is highly unpredictable, absent evidence or working examples in the specification or on record to show how to prevent a viral infection in a patient by administering an inhibitor of HMG-CoA reductase. Lack of a working example is a critical and crucial factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164. Thus, factual issues, i.e., working examples, are needed to comply with the enablement requirement of 112.

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation* to test any HMG-CoA reductase inhibitor compounds encompassed in the instant claims to be administered to a patient to prevent a viral infection in a patient, with no assurance of success.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement. Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9 and 13-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Baldini et al. (*Efficacy and tolerability of pravastatin for the treatment of HIV-1 protease inhibitors-associated hyperlipidemias: a pilot*), for same reasons of record stated in the Office Action dated August 26, 2004, and reiterated in full below.

Baldini et al. discloses administering the particular inhibitor of HMG-CoA reductase, pravastatin, to HIV-infected human patients who also administering protease inhibitors included ritonavir plus saquinavir, ritonavir, indinavir, saquinavir, ritonavir plus nelfinavir, and nelfinavir. Thus, the HIV-infected human patients taught by Baldini et al. meet the recitations or limitations of the subject herein, i.e., "said subject is or will become immunosuppressed"; "said subject suffers from severe combined immundefciency"; "said subject is taking or will take immunosuppressive drugs"; "said subject is or will be a transplant recipient"; "said subject has an existing viral infection" (emphases added). See abstract.

Note that Baldini et al. discloses that the effective amount of pravastatin to be administered is 20 mg/day (see abstract), which are within the effective amounts 10-40 mg/day for pravastatin, indicated in Applicant's specification (see page 17 line 12 of the specification).

Therefore, Baldini's method inherently inhibits infection of a cell by a virus in a subject, as claimed herein, since Baldini's method steps are same as the instant method steps, administering the same compound in the same amount to the same patient population. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Baldini et al. anticipates Claims 1-9 and 13-16.

Claims 1-9 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Aboulafia et al. (*Simvastatin-induced rhabdomyolysis in an HIV-infected patient with coronary artery disease*) , for same reasons of record stated in the Office Action dated August 26, 2004, and reiterated in full below.

Aboulafia et al. discloses administering the particular inhibitor of HMG-CoA reductase, simvastatin, to HIV-infected human. Thus, the HIV-infected human patients taught by Aboulafia et al. meet the recitations or limitations of the subject herein, i.e., "said subject is or will become immunosuppressed"; "said subject suffers from severe combined immundefciency"; "said subject is taking or will take immunosuppressive drugs"; "said subject is or will be a transplant recipient"; "said subject has an existing viral infection" (emphases added). See abstract.

Therefore, Aboulafia's method inherently inhibits infection of a cell by a virus in a subject, as claimed herein, since Aboulafia's method steps are same as the instant method steps, administering the same compound to the same patient population. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Aboulafia et al. anticipates Claims 1-9 and 13.

Claims 1-9 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Murillas et al. (*Atorvastatin: therapeutic use. Hyperlipidaemia In patients with HIV-1 infection receiving protease inhibitors*), for same reasons of record stated in the Office Action dated August 26, 2004, and reiterated in full below.

Murillas et al. discloses administering the particular inhibitor of HMG-CoA reductase, atorvastatin, to HIV-infected human patients who also receiving protease inhibitors. Thus, the HIV-infected human patients taught by Baldini et al. meet the recitations or limitations of the subject herein, i.e., "said subject <u>is or will</u> become immunosuppressed"; "said subject suffers from severe combined immundefciency"; "said subject <u>is taking or will take</u> immunosuppressive drugs"; "said subject is or <u>will be</u> a transplant recipient"; "said subject has an existing viral infection" (emphases added). See abstract.

Therefore, Murillas's method inherently inhibits infection of a cell by a virus in a subject, as claimed herein, since Murillas's method steps are same as the instant method steps, administering the same compound to the same patient population. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that even the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Murillas et al. anticipates Claims 1-9 and 13-16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maziere et al. (C24, PTO-1229 submitted June 11, 2002) and Murillas et al. or Baldini et al. in view of Graham et al. (WO 99/62932) and Mills , for same reasons of record stated in the Office Action dated August 26, 2004, and reiterated in full below.

Maziere et al. teaches that HMG-CoA reductase inhibitors, such as lovastatin, are useful in a method of inhibiting HIV infective cycle in AIDS patients since lovastatin inhibits HIV-1 expression in H9 human T lymphocytes or viral multiplication. See in Maziere et al., the title, "Summary", and page 66 "Conclusion". Maziere et al. also teaches that the particular nucleoside analog, AZT, is known to be useful in treating viral infection by inhibiting viral replication in humans. See "Introduction" page 63 the left column.

The same disclosure of or Murillas et al. or Baldini et al. has been discussed in the 102(b) rejection set forth above (supra).

The Maziere et al., Murillas et al. and Baldini et al. do not expressly disclose the employment of HMG-CoA reductase inhibitors in a method of inhibiting infection of a cell by a virus which is respiratory syncytial virus (RSV) in a human, a non-human mammal, or a livestock animal. The above cited prior art does also not expressly disclose the employment of HMG-CoA reductase inhibitor in combination with ribavarin in a method inhibiting infection of a cell by a virus in a subject.

Graham et al. (WO 99/62932) teaches that the enveloped viruses including RSV and HIV share a common cellular entry mechanism-fusion of the viral envelop; the cell membrane-the RhoA peptides inhibit viral entry for other viruses which are demonstrated to share the cellular entry mechanism common to RSV and HIV (see page 5 lines 5-15).

Mills teaches that ribavarin is a known licecned antiviral agent or drug for RSV infections. The combination of ribavarin and other antiviral agents are also known in the art. See page 39-41.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a HMG-CoA reductase inhibitor in a method of inhibiting infection of a cell by a virus such as RSV in a human, a non-human mammal, or a livestock animal, and to employ a HMG-CoA reductase inhibitor in combination with ribavarin in a method of inhibiting infection of a cell by a virus.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a HMG-CoA reductase inhibitor in a method of inhibiting infection of a cell by a virus such as RSV in a human, a non-human mammal, or a livestock animal, since a HMG-CoA reductase inhibitor such as lovastatin is known to be useful in a method for inhibiting infection of a cell by a virus, i.e., inhibiting HIV infective cycle in AIDS patients, by inhibiting HIV-1 expression in H9 human T lymphocytes or viral multiplication according to Maziere et al. Moreover, HMG-CoA reductase inhibitors in combination with other antiviral agents such as protease inhibitors to be administered to HIV-infected human patients are known in the art according to Murillas et al. or Baldini et al.

Further, both RSV and HIV are the enveloped viruses and share a common cellular entry mechanism-fusion of the viral envelop, according to Graham et al. Thus,, one of ordinary skill in the art would have reasonably expected that lovastatin would also be able to inhibit RSV infective cycle and multiplication as it inhibits HIV infective

cycle and multiplication, since both RSV and HIV are the enveloped viruses and share a common cellular entry mechanism-fusion of the viral envelop.

Therefore, one of ordinary skill in the art would have reasonably expected that a HMG-CoA reductase inhibitor would have a beneficial therapeutic effect in inhibiting infection of a cell by a virus such as RSV in a human, a non-human mammal, or a livestock animal.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to add ribavarin in a method of inhibiting infection of a cell by a virus such as RSV, since ribavarin is known to be useful in treating viral infection including RSV by inhibiting viral replication in humans, and combination therapy for treating viral infections is well known in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

It is noted that Applicant has not argued all prior art rejections of record stated in the Office Action dated August 26, 2004:

The rejection of Claims 1-9 and 13-16 made under 35 U.S.C. 102(a) as being anticipated by Baldini et al. (*Efficacy and tolerability of pravastatin for the treatment of HIV-1 protease inhibitors-associated hyperlipidemias: a pilot*);

The rejection of Claims 1-9 and 13 made under 35 U.S.C. 102(a) as being anticipated by Aboulafia et al. (*Simvastatin-induced rhabdomyolysis in an HIV-infected patient with coronary artery disease*);

The rejection of Claims 1-9 and 13-16 made under 35 U.S.C. 102(b) as being anticipated by Murillas et al. (*Atorvastatin: therapeutic use. Hyperlipidaemia In patients with HIV-1 infection receiving protease inhibitors*).

The rejection of Claims 11 and 17-20 made under 35 U.S.C. 103(a) as being unpatentable over Maziere et al. (C24, PTO-1229 submitted June 11, 2002) and Murillas et al. or Baldini et al. in view of Graham et al. (WO 99/62932) and Mills (0f record).

Further, note that all rejections in the Office Action dated October 2, 2003 have been withdrawn in view of the appeal brief filed on May 26, 2004, PROSECUTION has bee REOPENED and a new ground(s) of rejection(s) set forth in the previous Office Action August 26, 2004.

Applicant's arguments filed on January 31, 2005 with respect to the prior art rejections in the Office Action dated October 2, 2003, now withdrawn, have been considered but are moot in view of the new ground(s) of rejections set forth in the previous Office Action August 26, 2004.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
April 6, 2005